

REMARKS

Claims 1-2 and 8-12 and 51-53 are pending in this application. Claim 50 has been withdrawn, and claims 51-53 added. Applicant respectfully requests reconsideration of the above-identified application in view of the argument below.

CLAIM OBJECTIONS

Applicant notes that the Examiner had maintained the rejection of claims 1-2, 8-12 and claim 50 under 35 U.S.C. § 112, first paragraph for the reasons set forth on pages 2-8 of the previous Office Action. Applicant continues to traverse these rejections for the following reasons.

The Applicant again thanks the Examiner for the telephonic interviews, and summarizes the pending issues below.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. (MPEP § 2164.01).

The Examiner has not met her burden. As set forth in MPEP § 2164.04, the burden is on the Examiner under the enablement requirement to establish a reasonable basis to question the enablement provided for the claimed invention. The teaching in the specification must be taken to be in compliance with the enablement requirements of 35 U.S.C. § 112, first paragraph, unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

As discussed in the MPEP § 2164.05, the language of the Examiner's rejection should focus on those factors, reasons and evidence that lead the Examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation. The Examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. References should be supplied if possible to support a prima facie case of lack of enablement, but are not always required. However, technical reasons are always required. MPEP § 2164.05, and *In re Marzocchi*, supra.

The Response that was sent to the Examiner on May 4, 2004 was further discussed during the telephonic interviews. Pending claims 1-2, 8-12 and 50 were discussed in view of the 35 USC §112, ¶1 enablement rejection maintained by the Examiner.

First, during the subsequent July 21st teleconference, the Examiner stated that she had reconsidered the finality of the present pending Final Office Action, and agreed to remove the finality. Applicant thanks the Examiner for her consideration of this issue, and the removal of the finality of the pending Office Action.

Second, the Examiner indicated that there were outstanding issues remaining after the first portion of the telephone interview held June 23, 2004. The Examiner indicated that with respect to the pending enablement rejection that the scope of claim 1 with respect to the term "osteogenic cells" remains in dispute, and the scope of claim 50 with respect to the members of the Markush group remain in dispute.

Applicant's attorney referred Examiner to the pending Response to Office Action, Pages 9-10 with respect to these issues. Specifically, the Applicant notes that the Examiner has failed to provide any evidence that one of skill in the art would not find the pending claims enabled as to their present scope. Nonetheless, Applicant's attorney noted that additional examples could be provided to support Applicant's position that the scope of claim 1 with respect to the term "osteogenic cells" is justified by the knowledge and acceptance by those of skill in the art as to the use of calvarial cells as a model system for osteogenic bone physiology, regardless of whether the origin of the osteogenic cells as endochondral or intramembraneous. (See generally, Kuberasampath '844, Harris, et al '690, Bellows, et al 1989)

In one example, Kuberasampath '844 (filed March 20, 1995) discloses the use of fetal rat calvarial primary cultures (col. 25:12-33), and received claims not limited to either intramembraneous or endochondral bone (See col. 93:22-96:45).

In another example, Mundy '019 (filed June 10, 1998) discloses the use of *in vitro* (Example 2) and *in vivo* studies neonatal mouse calvaria, and received claims to methods to "enhance bone formation in vertebrate animals," not limited to an effect in either intramembraneous or endochondral bone (See col. 18:59-20:6).

In another example, Petrie '998 (filed Dec. 2, 1999) discloses *in vivo* calvarial bone growth data (Example 3, col. 28:58), and chondrogenic activity assay on cartilage cell line (TMC-23; Example 4), and received claims to methods to treat "vertebrate animals characterized by a deficiency in, or need for, bone growth replacement and/or an undesirable level of bone resorption...", not limited to either intramembraneous or endochondral bone (See col. 29:50-36:25).

Therefore, the Applicant provides at least three examples in which contemporaneous applicants were not limited to claims to a particular cell type or origin of the cell type demonstrated in the examples in the specification. These examples, provide evidence that those skilled in the art understood that fetal calvarial cells are a model system for bone physiology generally, and that examples using fetal calvarial cell model were sufficiently enabling for claims not limited to calvarial cells, or osteogenic cells derived from endochondral or intramembraneous bone, but to osteogenic cells or bone generally. If the Examiner maintains the enablement rejection with respect to claim 1, Applicants request that the Examiner provide technical reasons to support her contentions per MPEP §2164.01.

Further, the Applicant notes that the Examiner has failed to provide any evidence that one of skill in the art would not recognize that fetal calvarial cells include a heterogeneous population of cells including members included in claim 50. Nonetheless, Applicant's attorney noted that additional examples could be provided to support Applicant's position that the scope of new claim 52.

Bellows, et al. 1989 provides evidence that one of skill in the art would know that fetal calvarial cells include a heterogeneous mixture of cells including fibroblasts, chondrocytes, undifferentiated mesenchymal cells and cells at various stages of osteoblast differentiation. (Also see for example, Hoshi, et al. 1997, at pages 158-160 disclosing that mesenchymal cells in general are osteogenic) Further, Bellows, et al. discloses that fetal calvarial cells include the cell lineage from stem cells to osteocytes. Finally, Bellows, et al disclose that chondrocytes are derived from chondroblasts, also present in fetal calvarial cultures.

Also, Burger, et al 1986 disclose osteoblasts and osteoclasts are derived from bone marrow cells, also present in calvarial cultures. Finally, Takagi, et al 1982 disclose dural cells are osteogenic, and are found in fetal calvarial cell cultures (Opperman, et al. 1997).

In summary, the Applicant respectfully maintains that the teachings of the specification, in combination with knowledge of those skilled in the art, provide ample guidance to enable those skilled in the art to make and use the invention. Because the Examiner has not met the burden under the enablement requirement, and in view of the arguments set forth above, the rejection of the pending under 35 U.S.C. § 112, first paragraph, should be withdrawn.

CONCLUSION

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501946 and please credit any excess fees to such deposit account; please reference attorney docket no. 38586-329.

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Respectfully submitted,
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